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Ms. Nancy Chamberlain
Center for Drug Evaluation and Research (HFD-21)
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

Dear Ms. Chamberlain:

I am writing to express my professional opinion regarding the use of opioid medication in the adult chronic non-cancer pain population. By way of background, please accept the following summary of my professional credentials. I am Board Certified in the field of Physical Medicine and Rehabilitation since 1991, by the American Board of Physical Medicine and Rehabilitation. In addition, I am certified in the medical subspecialty of Pain Management also by the American Board of Physical Medicine and Rehabilitation since 2000 (the first year this subspecialty certification was available for physiatrists). In addition, I hold voluntary certifications by the American Board of Electrodiagnostic Medicine in Electrodiagnostic Medicine and by the American Board of Independent Medical Examiners as an Independent Medical Examiner. The bulk of my patient population falls into the category of adult chronic non-cancer pain. This includes pain secondary to personal injury, work-related accidents, as well as pain secondary to injury and illness in non-adversarial settings. I have been Medical Director of several chronic pain treatment centers at Loma Linda University Medical Center in California as well as at Sinai Hospital of Baltimore where I currently practice. As of July 1st I will be assuming the role of Chairman of the Department of Physical Medicine and Rehabilitation at Sinai Hospital of Baltimore.

I wish to express my concern regarding the possibility of blanket regulations regarding the use of opioid medications for adult chronic non-cancer pain. As with most other chronic diseases, chronic pain is a complex phenomenon. It usually requires a multi-disciplinary approach as well as attention not only to issues of underlying disease or injury but also secondary physical and psychological impairments as well as disabilities. A multi-dimensional multi-disciplinary approach is becoming the standard of care for chronic pain management. In addition to interventions such as physical restoration with physical therapy, psychological intervention and counseling, invasive procedures, and alternative medicine treatments, a wide pharmacological array is also utilized. This includes and should include opioid medications.

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Opioid treatment for chronic non-malignant pain is not a straight-forward matter. It most definitely requires careful consideration and careful monitoring. It can be the solution for many patients or become the problem for others. It is I believe extremely important to differentiate the effects of opioids on individuals including the differences between tolerance dependence addiction and pseudo addiction. Preventing abuse and diversion are the responsibility of the prescribing physician. It is for this reason that many clinicians, including myself, utilize a treatment agreement with patients who require ongoing opioid medication for a chronic pain problem. In addition, there is substantial medical literature to suggest that opioids are less potentially toxic than anti-inflammatories and acetaminophen, and that formulations that allow around-the-clock dosing provide better overall pain management and reduce the risk of physiologic and psychological tolerance and dependence. Proper stable dosing should be a formal stated goal of treatment.

In my opinion, of much greater threat to patients with chronic non-malignant pain is the lack of medical resources available to most patients due to insurance or Worker's Compensation law that makes it extremely difficult to implement a multi-disciplinary management approach that is often required.

It is my sincere hope that the Food and Drug Administration will take a careful and balanced approach to reviewing this issue that includes input from professionals in chronic pain management and from organizations dealing with this issue. I am therefore hopeful that the FDA will not implement a blanket restriction that will exacerbate the suffering of millions of Americans unnecessarily because of the irresponsible misuse of opioid medications by the small minority and by those whose underlying disease of addiction goes untreated.

Sincerely,



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